Appendix 4: Risk of Bias Assessment

Cochrane Risk of Bias Tool

Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Selective Reporting (reporting bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Other bias
Korbkitjaroen et al (2011)	Unclear risk Reason: randomisation mentioned but method no specified	Unclear risk Reason: randomisation mentioned but method no specified	Low risk Reason: All pre-specified outcomes reported	High risk Reason: no blinding	Unclear risk Reason: not specified	Low risk Reason: no missing data	High risk Reason: did not control for possible confounders or adjust for clustering within the wards

Newcastle-Ottawa Risk of Bias Tool for Cohort Studies

Study: Chen et al, 2015	Score
Selection	
1) Representativeness of the exposed cohort?: a) truly representative of the average pre-term infant in the community * b) somewhat representative of the average pre-term infant in the community * c) selected groups of users e.g. nurses, volunteers d) no description of the derivation of the cohort	(b) = 1 point
2) Selection of the non-exposed cohort: a) drawn from the same community as the exposed cohort * b) drawn from a different source c) no description of the derivation of the non-exposed cohort	(a) = 1 point
3) Ascertainment of exposure: a) secure record (e.g. surgical records) * b) structured interview * c) self-written report d) no description	(a) = 1 point
4) Demonstration that an outcome of interest was not present at the start of a study: a) Yes * b) No	(a) = 1 point
Comparability	

1) Comparability of cohorts on the basis of the design or analysis: a) study controls for age and sex (select the most important factor) * b) Study controls for any additional factor * (This criterion could be modified to indicate specific control for a second important factor.) c) Cohorts are not comparable on the basis of the design or analysis controlled for confounders	(c) = 0 points
Outcome	
1) Assessment of outcome: a) independent blind assessment * b) record linkage * c) self-report d) no description	(a) = 1 point
2) Was follow-up long enough for outcomes to occur? a) yes (select an adequate follow up period for outcome of interest) * b) no	a) = 1 point
3) Adequacy of follow-up of cohorts a) complete follow up - all subjects accounted for * b) subjects lost to follow up unlikely to introduce bias - small number lost - > ____ % (select an adequate %) follow up, or description provided of those lost) * c) follow up rate < ____% (select an adequate %) and no description of those lost	(d) = 0 points

d) no statement	
Total score	6 points

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

Newcastle-Ottawa Risk of Bias Tool for Case-Control Studies

Study: Raza and Avan, 2013	Score
Selection	
1) Is the case definition accurate?: a) yes, with independent validation* b) yes, e.g. record linkage or based on self reports c) no description	(a) = 1 point
2) Representativeness of the cases: a) consecutive or obviously representative series of cases * b) potential for selection biases or not stated	(a) = 1 point
3) Selection on controls: a) community controls * b) hospital controls c) no description	(a) = 1 point
4) Definition of controls: a) No history of disease (endpoint)* b) No description of source	(b) = 0 point
Comparability	
1) Comparability of cases and controls on the basis of the design or analysis: a) study controls for gender, area of residence, date of birth * b) Study controls for any additional factor – area of residence and date of birth*	(a) = 1 points (b) = 1 points

c) Cases and controls are not comparable on the basis of the design or analysis controlled for confounders	
Exposure	
1) Ascertainment of exposure: a) a secure record (e.g. surgical record) * b) structured interview where blind to case/control status * c) interview not blinded to case/control status d) written self-report or medical record only e) no description	(a) = 1 point
2) Same method of ascertainment for cases and controls? a) yes * b) no	a) = 1 point
3) Non-response rate a) same rate for both groups * b) non-respondents described c) rate different and no designation	(c) = 0 points
Total score	7 points

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability